

REMARKS

Claims 28-39, 46 and 75 are pending in this application.

According to the Official Action, claims 28-39, 46 and 75 are rejected under 35 USC 102(b) based on NZ 282898 cited in the previous response. This is respectfully traversed.

It is applicant's position that the Examiner's rejection is based on her reference to various embodiments in the reference that have been taken out of context. In the previous response the differences between the claims in this application and the disclosure of NZ 282898 were described.

The Examiner cites 282898 in her objection on page 2 but then continues to cite 282893. We assume that this is an error and that NZ 282898 is the correct reference. This was raised in the previous response and has not been addressed by the Examiner.

There are clear and substantial differences between the fractions of the present invention compared to those obtained from following the disclosure of the reference. The fractions claimed in this application are obtained by ultrafiltration and those of the reference are an eluted fraction from a chromatography column which is subsequently subjected to ultrafiltration.

In the Examiner's "Response to Arguments" she refers to Example 7, line 18 and line 20 when a composition containing IGF-1 is obtained. Applicant submits that the composition in the reference is *vastly* different than that of the present invention. The IGF-1

containing composition of the reference is obtained after the colostrum is run through an S-spherosil column. The IGF-1 is adhered to the column and finally eluted after the colostrum has passed and washed through the column. In fact, the excess colostrum is washed through the column with de-ionized water after which the adhered IGF-1 is then eluted.

The IGF-1 that is adhered and eluted from the column which is then subjected to ultrafiltration is not equivalent to the "retentate" of the present invention. The processes described in the reference are distinguished from the processes of the present invention which initially subjects the colostrum to ultrafiltration thereby fractionating colostrum by size rather than charge or by ion exchange chromatography. Different proteins and fractions will be retained if chromatography rather than ultrafiltration is used. Whilst it is agreed that IGF-1 will be present in both colostrum fractions, the ratios of IGF-1 to other factors in the fraction will be different.

An ultrafiltration unit will retain the IGF-1 and other molecules of the same size and larger in a retentate. An ion-exchange chromatography will retain IGF-1 and other molecules of similar charge. Larger molecules not having the same charge may pass through the column. Hence, the two processes retain different factors.

The Examiner states:

"A colostrum sample, as disclosed by the reference, and subjected to the

identical steps of ultrafiltration and spray drying will yield a composition as claimed because in the eluate an amount of colostrum will still be present".

The steps are not identical because different fractions are obtained and processed.

In the reference, ultrafiltration is conducted on the eluate which will comprise different molecules to that of colostrum. In fact, the colostrum is "washed out" with deionized water. The remaining residues cannot be described as colostrum. The term "colostrum" is understood by the skilled addressee to contain all of the components that make up whole "colostrum". It is not an eluate that has been pre-processed through a chromatography column. Even if the eluate still retains some components of colostrum, it does not retain all of the components of colostrum nor does it retain the same components of colostrum. Hence it is not colostrum that is obtained in the cited reference. The steps of ultrafiltration and spray drying are performed on distinctly different compositions and will not yield the same composition.

The Examiner also states:

"Thus, a powdered composition containing IGF-1 is identical to a colostrum fraction as claimed because applicants own specification teaches that the composition is a powder, note page 8, line 8".

Just because a powder is obtained from a fraction of colostrum does not mean that they would be the same. Powders can be obtained from many different compounds and compositions and it is clear not all of these powders are the same.

The Examiner states:

'Therefore, the reference does not just use IGF-1 that uses a composition containing IGF-1 to improve physical work. The claims read on such a composition containing IGF-1 because the same process steps are practiced on colostrum and a powdered composition containing IGF-1 is obtained':

While the process of ultrafiltration and spray drying are used, the same process steps are not used in the same sequence. As explained above, the process of the present invention requires subjecting colostrum (and not a fraction of the colostrum in the form of an eluate) to ultrafiltration to obtain a retentate. The resultant fractions are distinctly different (as described above by size and charge) thereby providing a distinctly different final product that is used to improve physical work capacity especially one or more of endurance, ability to do exercise, fatigue and recovery from exercise.

The present claims recite "subjecting colostrum to ultrafiltration" whereas the reference refers to the colostrum being run through a column and the bound IGF-1 being eluted. Then it is not the colostrum that undergoes ultrafiltration it is the eluate that undergoes ultrafiltration. This is a distinguishing point. Accordingly, the composition referred to in the present claims and that of the reference are different and therefore, a different composition is used for improving physical work capacity compared to that for providing a bone reinforcement effect which is useful for preventing and treating osteoporosis.

As anticipation requires that each and every element of the claimed invention be

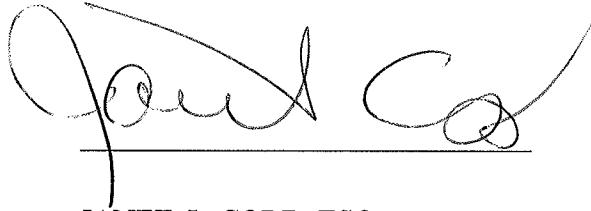
disclosed in a single prior art reference. *In re Paulsen*, 30 F.3d 1475, 31 USPQ 1671 (Fed. Cir. 1994) and there must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention. *Scripps Clinic & Res. Found. v. Genentech, Inc.*, 927 F.2d 1565, 18 USPQ2d 1001 (Fed. Cir. 1991), NZ282898 does not include all of the features of the claims and cannot anticipate the claims.

The claims currently under examination are novel in the light of NZ282898 and therefore, it is respectfully requested that the rejection be withdrawn.

Please charge Deposit Account 12-0425 for any fees which may be due by this paper.

It is submitted that the present application is in condition for allowance and favorable consideration is respectfully requested.

Respectfully submitted,



JANET I. CORD, ESQ.
LADAS & PARRY LLP
26 WEST 61ST STREET
NEW YORK, NEW YORK 10023
REG.NO.33,778(212)708-1935